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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG and LTS LOHMANN THERAPIE-SYSTEME AG Plaintiffs, v. ZYDUS NOVELTECH INC., ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD. (d/b/a ZYDUS CADILA) Defendants.	:	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG and LTS Lohmann Therapie-Systeme AG, for their Complaint against defendants Zydus Noveltech Inc., Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

6. On information and belief, defendant Zydus Noveltech Inc. ("Zydus Noveltech") is a corporation organized and existing under the laws of the State of New Jersey with a principal place of business at 1775 Williston Road, Suite 210, So. Burlington, VT 05403.

7. On information and belief, defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus Pharmaceuticals") is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business located at 73 Route 31 N., Pennington, NJ 08534.

8. On information and belief, defendant Cadila Healthcare Ltd. (d/b/a Zydus Cadila) ("Cadila") is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015 Gujarat, India. On information and belief, Zydus International Private Ltd., a wholly-owned subsidiary of

Cadila, owns 85% of Zydus Noveltech. On information and belief, Zydus Pharmaceuticals is a wholly-owned subsidiary of Zydus International Private Ltd.

9. On information and belief, the acts of Zydus Noveltech complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Zydus Pharmaceuticals and Cadila.

10. Defendants Zydus Noveltech, Zydus Pharmaceuticals, and Cadila are referred to collectively herein as "Zydus."

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

12. On information and belief, Zydus Noveltech is involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals. On information and belief, Zydus Noveltech, Zydus Pharmaceuticals, and Cadila each act as agents of each other and/or work in concert with each other to further the aims of Cadila. On information and belief, Zydus Noveltech, which is responsible for, *inter alia*, developing and submitting abbreviated new drug applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA"), relies on contributions from Zydus Pharmaceuticals and Cadila.

13. On information and belief, Zydus Pharmaceuticals is the United States division of Cadila. On information and belief, Zydus Noveltech acts on behalf of Cadila in the United States to develop and market drug products.

14. On information and belief, Zydus Noveltech and Zydus Pharmaceuticals are corporations organized and existing under the laws of New Jersey and have purposely availed

themselves of the rights and benefits of New Jersey law and this Court. On information and belief, Zydus Pharmaceuticals has a principal place of business located at 73 Route 31 N., Pennington, NJ 08534. This Court has personal jurisdiction over Zydus Noveltech and Zydus Pharmaceuticals for these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged.

15. On information and belief, Zydus Noveltech, Zydus Pharmaceuticals, and Cadila are in the business of manufacturing, marketing, importing into the United States and/or selling pharmaceutical drug products, including generic drug products. On information and belief, Cadila and Zydus Noveltech directly or through their affiliates and agents, including Zydus Pharmaceuticals, market and sell drug products throughout the United States and in this judicial district, and have purposely availed themselves of the rights and benefits of New Jersey law and this Court.

16. On information and belief, Zydus Noveltech, Zydus Pharmaceuticals, and Cadila share common directors.

17. This Court has personal jurisdiction over Zydus Pharmaceuticals and Cadila because they have affirmatively availed themselves of the jurisdiction of this Court by filing counterclaims in this district, and have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g.*, *Otsuka Pharm. Co. v. Zydus Pharms. USA Inc. et al.*, 1:14-cv-03168 (D.N.J.) (defendants and counterclaimants); *Actelion Pharms. Ltd. et al. v. Apotex Inc. et al.*, 1:12-cv-05743 (D.N.J.) (intervenor-defendants and counterclaimants); *Depomed, Inc. v. Zydus Pharms. (USA) Inc. et al.*, 3:12-cv-02813 (D.N.J.) (defendants and counterclaimants); *Takeda Pharm. Co. et al. v. Zydus Pharms. (USA) Inc. et al.*, 3:10-cv-01723 (D.N.J.) (defendants

and counterclaimants); *Teva Pharm. Indus. Ltd. et al. v. Zydus Pharms., Inc. et al.*, 3:07-cv-04942 (D.N.J.) (defendants and counterclaimants).

18. This Court has personal jurisdiction over Zydus by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of the laws of New Jersey by engaging in systematic and continuous contacts with New Jersey.

19. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF – PATENT INFRINGEMENT

20. Plaintiff NPC holds an approved new drug application ("NDA") No. 22-083 for Exelon® Patch (rivastigmine transdermal system or extended release film) (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths), which patch contains the active ingredient rivastigmine. Exelon® Patch (4.6 mg/24 hr and 9.5 mg/24 hr dosage strengths) was approved by the FDA on July 6, 2007, and Exelon® Patch (13.3 mg/24 hr dosage strength) was approved by the FDA on August 31, 2012. Exelon® Patch is indicated for the treatment of mild to moderate dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease. Exelon® Patch (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths) is sold in the United States by Plaintiff NPC.

21. Rivastigmine is known chemically as (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate.

22. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,316,023 ("the '023 patent"). The '023 patent was duly and legally issued on November 13, 2001.

23. The '023 patent claims pharmaceutical compositions, *inter alia*, comprising 1 to 40 weight percent of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in the form of a free base or acid addition salt, 0.01 to 0.5 weight percent of an antioxidant, and a diluent or carrier, wherein the weight percents are based on the total weight of the pharmaceutical composition, as well as transdermal devices. A true copy of the '023 patent is attached hereto as Exhibit A.

24. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,335,031 ("the '031 patent"). The '031 patent was duly and legally issued on January 1, 2002.

25. The '031 patent claims pharmaceutical compositions, *inter alia*, comprising: (a) a therapeutically effective amount of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form; (b) about 0.01 to about 0.5 percent by weight of an antioxidant, based on the weight of the composition, and (c) a diluent or carrier, as well as transdermal devices and methods of stabilizing (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form. A true copy of the '031 patent is attached hereto as Exhibit B.

26. The '023 and '031 patents were initially assigned to Novartis AG and LTS Lohmann Therapie-Systeme GmbH & Co. KG, which subsequently changed its legal form to become Plaintiff LTS.

27. On information and belief, Defendant Zydus submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of a rivastigmine transdermal

system, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths ("Zydus's ANDA Products") before the expiration of the '023 and '031 patents.

28. On information and belief, Zydus made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '023 and '031 patents are invalid and/or will not be infringed. Zydus did not allege that any of the '023 or '031 patent claims were unenforceable.

29. Plaintiffs received written notification of Zydus's ANDA and its accompanying 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification by a letter dated July 16, 2014 ("Notice Letter").

30. This action was commenced within 45 days of receipt of Zydus's Notice Letter.

31. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Zydus's ANDA Products before the expiration of the '023 and '031 patents, Zydus has committed an act of infringement under 35 U.S.C. § 271(e)(2).

32. On information and belief, when Zydus filed its ANDA, it was aware of the '023 and '031 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the '023 and '031 patents was an act of infringement of those patents.

33. On information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Products will infringe and/or induce infringement of one or more claims of the '023 and '031 patents.

34. On information and belief, Zydus's ANDA Products, if approved, will comprise a pharmaceutical composition. Zydus, in its Notice Letter, did not deny that its ANDA Products, if approved, will contain a pharmaceutical composition.

35. On information and belief, Zydus's ANDA Products, if approved, will be transdermal devices. Zydus, in its Notice Letter, did not deny that its ANDA Products, if approved, will be transdermal devices.

36. On information and belief, Zydus's ANDA Products, if approved, will comprise a pharmaceutical composition comprising (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in the form of a free base ("rivastigmine"). On information and belief, Zydus's ANDA Products, if approved, will comprise a pharmaceutical composition comprising 1 to 40 weight percent of rivastigmine, wherein the weight percent is based on the total weight of the pharmaceutical composition. On information and belief, Zydus's ANDA Products, if approved, will comprise a pharmaceutical composition comprising a therapeutically effective amount of rivastigmine. Zydus, in its Notice Letter, did not deny that its ANDA Products, if approved, will contain rivastigmine or the claimed amounts of rivastigmine.

37. On information and belief, Zydus's ANDA Products, if approved, will contain an antioxidant. Zydus, in its Notice Letter, did not deny that its ANDA Products, if approved, will contain an antioxidant.

38. On information and belief, Zydus's ANDA Products, if approved, will contain butylhydroxytoluene.

39. On information and belief, Zydus's ANDA Products, if approved, will comprise a pharmaceutical composition comprising 0.01 to 0.5 weight percent of an antioxidant wherein the weight percent is based on the total weight of the pharmaceutical composition. On

information and belief, Zydus's ANDA Products, if approved, will comprise a pharmaceutical composition comprising about 0.01 to about 0.5 percent by weight of an antioxidant, based on the weight of the pharmaceutical composition.

40. On information and belief, Zydus's ANDA Products, if approved, will comprise a pharmaceutical composition comprising a diluent or carrier. Zydus, in its Notice Letter, did not deny that its ANDA Products, if approved, will contain a diluent or carrier.

41. On information and belief, Zydus's ANDA Products, if approved, will contain an amount of antioxidant effective to stabilize rivastigmine from oxidative degradation.

42. On information and belief, Zydus, if its ANDA Products are approved, will practice a method of forming a composition by combining rivastigmine with an antioxidant.

43. On information and belief, the commercial manufacture of Zydus's ANDA Products will involve direct infringement of the '023 patent. On information and belief, this will occur at Zydus's active behest, and with Zydus's intent, knowledge and encouragement. On information and belief, Zydus will actively induce, encourage and abet this infringement with knowledge that it is in contravention of the rights under the '023 patent.

44. On information and belief, the commercial manufacture of Zydus's ANDA Products will involve direct infringement of the '031 patent. On information and belief, this will occur at Zydus's active behest, and with Zydus's intent, knowledge and encouragement. On information and belief, Zydus will actively induce, encourage and abet this infringement with knowledge that it is in contravention of the rights under the '031 patent.

45. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Zydus's ANDA Products be a date that is not earlier than January 8, 2019, the

expiration date of the '023 and '031 patents, and an award of damages for any commercial sale or use of Zydus's ANDA Products and any act committed by Zydus with respect to the subject matter claimed in the '023 and '031 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

46. On information and belief, Zydus has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Products, including seeking approval of that product under Zydus's ANDA.

47. There is a substantial and immediate controversy between Plaintiffs and Zydus concerning the '023 and '031 patents. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Zydus will infringe and/or induce infringement of one or more claims of the '023 and '031 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Zydus has infringed and induced infringement of one or more claims of the '023 and '031 patents by filing the aforesaid ANDA relating to Zydus's rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths;

B. A permanent injunction restraining and enjoining Zydus and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of a rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths, as claimed in the '023 and '031 patents;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Zydus's rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths, be a date that is not earlier than the expiration of the right of exclusivity under the '023 and '031 patents;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths, will infringe one or more claims of the '023 and '031 patents and that Zydus will induce infringement of one or more claims of the '023 and '031 patents;

E. Damages from Zydus for the infringement and inducement of infringement of the '023 and '031 patents;

F. The costs and reasonable attorney fees of Plaintiffs in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: August 28, 2014

McCARTER & ENGLISH, LLP

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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG and LTS Lohmann Therapie-Systeme AG, by their attorneys, hereby certify pursuant to Local Rule 11.2 that the matter in controversy is the subject of the following pending actions:

(1) *Novartis Pharmaceuticals Corporation, et al. v. Par Pharmaceutical, Inc.*, C.A. No. 11-1077-RGA (D. Del.);

(2) *Novartis Pharmaceuticals Corporation, et al. v. Noven Pharmaceuticals, Inc., et al.*, C.A. No. 13-527-RGA (D. Del.);

(3) *Novartis Pharmaceuticals Corporation, et al. v. Par Pharmaceutical, Inc.*, C.A. No. 13-1467-RGA (D. Del.);

(4) *Novartis Pharmaceuticals Corporation, et al. v. Noven Pharmaceuticals, Inc., et al.*, C.A. No. 14-111-RGA (D. Del.);

(5) *Novartis Pharmaceuticals Corporation, et al. v. Mylan Inc., et al.*, C.A. No. 14-777-RGA (D. Del.);

(6) *Novartis Pharmaceuticals Corporation, et al. v. Mylan Inc., et al.*, C.A. No. 14-106-IMK (N.D. W. Va.);

(7) *Par Pharmaceutical, Inc. v. Novartis Pharmaceuticals Corporation, et al.*, C.A. No. 14-843-RGA (D. Del.); and

(8) *Novartis Pharmaceuticals Corporation, et al. v. Zydus Noveltech Inc., et al.*, C.A. No. 14-1104-UNA (D. Del.).

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: August 28, 2014

McCARTER & ENGLISH, LLP

s/ William J. O'Shaughnessy

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